K062351

510(K) SUMMARY

FOR

Syngo® Dual Energy

OCT - 5 2006

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

August 9, 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Mr. Gary Johnson
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
Malvern, PA 19355
Phone: (610) 448-1778
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2. Device Name and Classification

Product Name:	*syngo® Dual Energy*
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

3. Substantial Equivalence:

The *syngo® Dual Energy* software package that is addressed in this premarket notification, is substantially equivalent to the following commercially available Siemens Medical Systems devices:

Manufacturer	Product	510(k)	Clearance date
1. Siemens	Leonardo *(syngo Fused Vision 3D)*	K040970	07/08/04
2. Siemens	InSpace 4D	K043469	02/03/05
3. Siemens	Body Perfusion	K050867	04/14/05
4. Siemens	SOMATOM DR I	K837107	03/09/83
(Remark:	*The referenced Predicate Device of the SOMATOM DHR has been cleared with a non-filing-justification in October 10, 1984 !)*		

4. Device Description:

Dual Energy CT can be used to obtain intensity measurements with two different spectra and thus provides additional information when compared to single energy. The post-processing application Syngo Dual Energy uses this additional information to improve the visualization of various energy dependent materials in the human body.

5. Indications for Use:

With the post-processing application *syngo® Dual Energy* it is possible to obtain additional information about the chemical composition of body materials. CT images taken at the same time with two different kV levels from the same patient and the same anatomical region are used and the differences in the energy dependence of the attenuation coefficients of different materials are exploited.

These images will be combined and analyzed to visualize information about anatomical and pathological structures.

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 5 2006

Mr. Gary Johnson
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
MALVERN PA 19355

Re: K062351
Trade/Device Name: Syngo® Dual Energy
Regulation Number: 21 CFR 892.1750
Regulation Name: Accessory to computed tomography system
Regulatory Class: II
Product Code: JAK
Dated: August 9, 2006
Received: August 11, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3
INDICATION FOR USE

510(k) Number (if known): K062351

Device Name: **Syngo® Dual Energy**

Syngo Dual Energy is designed to operate with Siemens Dual Source CT scanners. CT images taken at the same time, using two different kV levels, of the same anatomical region of a patient are used. Depending on the region of interest, contrast agents may be used. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials.
The images are combined to visualize and analyze information about anatomical and pathological structures

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ☐

(Per 21 CFR §801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062351